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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/074,181  | 02/12/2002  | Judith Aronhime      | 1662/56002            | 4579             |
| 26646   | 7590        | 04/19/2006           | EXAMINER              |                  |
| KENYON & KENYON LLP<br>ONE BROADWAY<br>NEW YORK, NY 10004 |             |                      | COLEMAN, BRENDA LIBBY |                  |
|   |             |                      | ART UNIT              | PAPER NUMBER     |
|   |             |                      | 1624                  |                  |

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/074,181             | ARONHIME ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Brenda L. Coleman      | 1624                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 January 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-11,13-20,22-33 and 35-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 2-11,13-20,22-33 and 35-57 is/are allowed.
- 6) Claim(s) 58-60,63,64 and 68-72 is/are rejected.
- 7) Claim(s) 61,62 and 65-67 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 2-11, 13-20, 22-33 and 35-72 are pending in the application.

This action is in response to applicants' amendment filed January 27, 2006.

Claims 45, 58, 68, 70 and 71 have been amended.

### ***Response to Amendment***

Applicant's amendments filed January 27, 2006 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 68, 69, 71 and 72 labeled paragraph 1 maintained in the last office action, the applicants' arguments have been fully considered and are sufficient to overcome the rejection of claims 68 and 69, however they were not found persuasive with respect to claims 71 and 72. Applicants' stated that it is commonly known in the field that drugs for the treatment of seizures, i.e. oxcarbazepine, are central-nervous system depressants and therefore claims 71, as amended and 72, directed to a method of treatment for depressing the central nervous system are also enabled. However, the claim language of claim 71 is such that the method of treatment for depressing the central nervous system and claim 72 wherein the central nervous system is depressed by blocking voltage sensitive sodium channels encompasses more than just seizures.

Claims 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 58-64, 68, 69 and 71 of the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. Applicants' stated that claim 58, as amended, requires the pharmaceutical composition to contain crystalline oxcarbazepine and that the crystalline forms and structures of oxcarbazepine in the pharmaceutical compositions of the present invention are therefore required to be retained. However, the applicants are not specifically claiming solid pharmaceutical compositions, but pharmaceutical compositions comprising crystalline oxcarbazepine and a pharmaceutically acceptable excipient. The specification on page 13 discusses the liquid pharmaceutical compositions of the instant invention, which would no longer possess the crystalline oxcarbazepine. Claim 58 fails to specifically claim a solid pharmaceutical composition.

Claims 58-60, 63, 64, 68, 69 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHINDLER, U.S. Patent No. 3,716,640, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1, 12, 21, 33, 58-64 and 68-71 of the last office action, the applicants' arguments have been fully considered and are sufficient to overcome the rejection of claims 33, 61, 62 and 65-67, however they were not found persuasive with respect to claims for claims 58-60, 63, 64

and 68-71. Applicants' stated that Boireau et al., reference, which discloses only a method of treating Parkinsonian syndrome using oxcarbazepine and fails to state the type of oxcarbazepine polymorph used and fails to disclose any process of preparing the oxcarbazepine polymorphs. However, the pharmaceutical compositions and method of use of oxcarbazepine of the instant invention are such that when a pharmaceutical compositions which comprises a crystalline oxcarbazepine and a pharmaceutically acceptable excipient no longer possesses the crystalline characteristics of the polymorphs. The specification on page 13 discusses the liquid pharmaceutical compositions of the instant invention, which would no longer possess the crystalline oxcarbazepine.

Claims 58-60, 63, 64 and 68-71 are rejected under 35 U.S.C. 102(b) as being anticipated by BOIREAU et al., U.S. Patent No. 5,658,900, for reasons of record and stated above.

***Claim Objections***

4. Claims 61, 62 and 65-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Allowable Subject Matter***

5. Claims 2-11, 13-20, 22-33 and 35-57 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds or the process of preparing the crystalline oxcarbazepines as claimed herein.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda L. Coleman  
Primary Examiner Art Unit 1624  
April 14, 2006